Colorado Department of Public Health and Environment
Health Facilities and Emergency Medical Services Division

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	PROVIDER IDENTIFICATION NUMBER:	MULTIPLE CONSTRUCTION	DATE SURVEY COMPLETED
	060064	BUILDING:	04/17/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CENTURA HEALTH-PORTER ADVENTIST HOSPITAL	**2525 S DOWNING ST DENVER 80210**

ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COMPLETION DATE
H 000	6CCR 1011-1 Chapter IV General Hospitals Initial Comments A survey prompted by complaint #CO21404 and #CO21664 was completed on 4/17/18. Deficiencies were cited.	H 000		
H 503	IV.5.101(3) Central Supplies: Personnel Sufficient supporting personnel shall be assigned to the service and properly trained in central medical-surgical supply services. This REGULATION is not met as evidenced by: Based on observations, interviews and document review, the facility failed to provide oversight and ensure sufficient staffing levels in the sterile processing department (SPD) were maintained to ensure appropriate techniques of sterilization process were completed as required. Furthermore, once the facility identified the failure in sterile processing there was no evidence of training or process improvements to avoid further incidents of contamination. This failure resulted in the delivery of numerous contaminated surgical instruments to operating room staff for use in surgical cases. Findings include: Facility Policy: The Sterile Processing Procedures policy read, all objects to be sterilized must first be thoroughly cleaned to remove all bio-burden and other residue. Instruments are to be inspected to ensure that they are clean, dry and functioning properly. References:	H 503	Tag H 503: Central Supplies, Personnel Person Responsible: The Governing Body will have ultimate responsibility for all corrective actions and ongoing compliance associated with these requirements, however the Chief Nursing Officer) CNO and Chief Medical Officer (CMO) provide direct oversight. The CNO and CMO collaborated regarding when the Sterile Processing Department staffing affected the availability of sterile instruments for scheduled surgeries. The Perioperative Services Director has direct oversight of the Sterile Processing Manager, who is responsible for the operational oversight of the SPD. Actions: 1. The Governing Board has full responsibility for determining, implementing and monitoring the Hospital's total operations and compliance with its policies and procedures. 2. The Governing Board was informed of the outcome of accreditation surveys	06/27/2018

I attest that the plan of correction will be implemented and monitored for compliance

AUTHORIZED PROVIDER REPRESENTATIVE'S SIGNATURE | TITLE | DATE

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H 503	Continued From page 1 According to the Association of periOperative Registered Nurses (AORN), Guidelines for Perioperative Practice, 2017: Recommendation II (Page 801), Items should be thoroughly cleaned and decontaminated before high-level disinfection. Cleaning and decontamination are the initial and most critical steps in breaking the chain of disease transmission. Debris, blood, mucus, fat, tissue, and organic matter will interfere with the action of the disinfectant. Recommendation I (Page 801), When critical items are contaminated with microorganisms, including bacterial spores, the risk of infection is substantial. Examples of critical items are surgical instruments. Recommendation XV (Page 841), Perioperative team members with responsibilities for cleaning and care of instruments used in surgery should receive initial and ongoing education and complete competency verification activities relate to cleaning and care of surgical instruments. Ongoing education and competency validation of perioperative personnel facilitate the development of knowledge, skills, and attitudes that affect patient and worker safety. Recommendation X (Page 829), Surgical instruments should be inspected and evaluated for cleanliness after decontamination and if soiled should be removed from service until they are cleaned. Items that are not clean can put a patient at risk for injury or surgical site infection (SSI). Use of instruments that are not thoroughly cleaned, poses a risk to patient safety. 1. The facility failed to provide oversight of the sterile processing department (SPD) staff to ensure equipment was completely cleaned, processed and sterilized appropriately by trainec	H 503	occurring 2/20/18 forward, via phone calls and meetings. The Governing Board held regular meetings and conference calls, late February forward, to discuss the survey findings and the plans of correction. 3. The Governing Board meets monthly and as necessary to discuss overall operational and patient care issues, related but not limited to, Sterile Processing Department personnel. Hospital leadership worked closely with Centura corporate leadership to assist with correction of survey findings and implementation of processes to sustain compliance. 4. Immediate SPD staffing plan developed to address variances in staffing levels, immediate staffing needs and considered skill sets required, surgical volume and instrument inventory, developed to staff SPD, 2/23/18. Staffing levels reviewed, new SPD staffing matrix developed with consideration of peak volume times, staff skill sets and instrument availability; staffing increased by 7 FTE positions, 2/28/18. Analyzed and balanced staffing across shifts in accordance with work volume. This includes at least 2 individuals staffed in decontamination to handle caseload, starting 4/13/18. Balanced, final staffing schedule created 4/20/18, including off-shift coverage. This “balanced” schedule is intended to smooth staffing over all shifts and days of the week, in response to case volumes. 5. Emergency shift bonus pay instituted on 2/21/18 to assist with immediate staffing requirements. Meetings to identify Corporate resources to assist with	

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H 503	Continued From page 2 and qualified personnel. a. A review of the Sterile Processing Department (SPD) Case Reports log, from 1/19/17 to 2/9/18 was conducted. During an interview with Clinical Nurse Specialist (CNS) #8, on 2/28/18 at 1:51 p.m., she stated the log contained data from SPD case reports which were completed by operating room staff who discovered an issue after the tray was delivered to the operating room (OR) suite. According to CNS #8 the reports were sent down to SPD and the SPD manager created the log. Review of the Case Report log revealed 17 of 22 SPD staff members had one or more incidents of documented contamination after the sterilization process which included bone, hair, blood, and cement. As example, Sterile Processing Technician (SPT) #13 had a total of 63 documented incidents involving concerns with trays processed from 1/19/17 to 2/9/18. From 1/19/17 to 3/28/17, SPT #13 had 17 reported incidents. Five of the 17 were contamination errors within a surgical tray (pan). On 1/24/17 chunks of bone found inside of the pan. On 2/16/17 cement was found on the instrumentation. On 3/8/17 visible bone and blood were found in the pan. On 3/22/17 bioburden was found while in a surgical case. On 3/27/17 hair was found on the white wrapping inside a piece of equipment used for knee surgery (knee bump). Subsequent to these incidents, on 3/28/17, SPT #13 received a written corrective action. Review of the corrective action revealed a written	H 503	immediate response, 2/22-23/18. 6. Ongoing collaboration continues with Centura, the hospital's corporate human resources department, to actively recruit and identify qualified SPD technicians. One SPD technician was hired as of 4/24/18. 2 additional fulltime SPD technicians will begin on 5/14/18. New technicians will complete orientation in 90-120 days, per policy. 7. Contracted agency supplies experienced and competent SPD technicians; 8 open positions filled. Travelers began 3/5/18 and are currently contracted through 7/12/18. 8. Experienced SPD Leads/Supervisors were identified and scheduled, starting 4/13/18, to provide 24/7 oversight of decontamination and sterilization processes. 9. An experienced Interim Perioperative Director identified on 3/4/18, to replace resigning Director 3/23/18. Interim dyad leadership structure created. One leader specifically focuses on the operational oversight and accountability of the SPD processes and staffing to ensure that sterile instruments are ready and available for scheduled cases. The other leader focuses primarily on OR processes and operations. Position for Perioperative Director posted 3/19/18. 10. The Perioperative Services Director notifies senior leadership when insufficient SPD staffing may result in unavailability of instrumentation for scheduled procedures/ surgeries. The OR schedule may be adjusted, as needed - Ongoing.	

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H 503	Continued From page 3 warning was issued for SPD#13's failure to meet the performance expectations of his position. Specifically, on 3/23/17 dirty Kerrisons (spinal surgical instruments) were found in an instrument set during a surgical case. The form noted on 3/7/17 the employee had received a verbal warning regarding dirty instrumentation in instrument sets. After the corrective action SPT #13 had 11 additional case reports that involved contaminated trays. As example, On 6/29/17 OR staff documented a dead bug was found in the surgical tray. On 8/1/17 and 8/9/17 cement was found on the cement gun (surgical instrumentation). On 8/28/17 crusty blood or tissue was found on a surgical instrument. On 9/6/17 cement was found on an instrument. On 11/22/17 blood from a previous surgical case was found on a piece of an instrument. On 3/1/18 at 7:06 a.m., an interview with SPT # 13 was conducted. SPT #13 stated SPD staff were currently recleaning, repackaging, and resterilizing every instrument in the department due to a recent incident in which surgical instruments were delivered to the OR suite which were not "up to standards" due to the "amount of bioburden" on them. b. Continued review of the Case Report log revealed SPT #18 had 12 incidents from 1/19/17 to 2/9/18 of documented contamination after the sterilization process; such as cement, bone and hair found on instruments or inside the tray. Specifically: On 1/19/17 two separate documented incidents of cement found on instruments. On 2/22/17 an incident of blood on a knife handle was noted. On 5/30/17 bone was found in the bottom of a	H 503	11. An experienced Interim SPD Manager was hired through contracted agency, starting 4/10/18, to manage staffing and oversee sterilization processes. The Interim SPD Manager reviews all occurrences and ensures staff is coached/trained and that corrective action is taken when appropriate. The Interim SPD Manager reports staffing issues that impact ability to process instrumentation needs, to the Perioperative Services Director. 12. Position for SPD Educator posted 3/19/18 and an interim educator was hired, starting 5/29/18. The SPD Educator assists with ongoing continuing education and competency assessment of SPD staff. Compliance and Monitoring: 1. Monitoring of completion of counseling/corrective action in relationship to each identified failure. Numerator = number of corrective actions documented related to failures monthly; Denominator = number of occurrence reports related to SPD process fall-out occurrences monthly, with a goal of 100% compliance. 2. Ongoing retraining and competency completion rate, for any SPD and OR staff not included in the initial training, is 100%. 3. Rate of completion of new-hire competencies by 90-120 days, per policy, for associates starting in February 2018, forward. This will be monitored monthly for 4 months and quarterly thereafter. 4. Daily monitoring of available SPD staff matching the staffing plan. Numerator = number of available SPD staff;	

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H 503	Continued From page 4 tray. On 6/1/17 an instrument was found to have dried blood on it. On 6/5/17, OR staff documented bioburden was found on a knee bump. On 6/14/17 white film was found on an instrument handle. On 6/28/17 black residue was found on an instrument. On 7/19/17, 8/9/17 and again on 8/22/17, cement was found left on instrumentation, all of which were found by OR staff in the OR suite. On 12/5/17 a foreign object (white lock) was documented as being found in a surgical tray. There was no documentation SPT #18 received retraining to prevent further failures identified from case reports. c. According to the case reports, from 1/25/17 to 1/23/18, SPT #19 had 10 incidents of contamination errors including blood, bone and rust found on the instruments and inside surgical trays. On 1/25/17 an instrument was noted as clogged with the previous patient's blood. On 1/26/17 blood was found on a drill bit. On 2/16/17 and 3/1/17 cement was found on instrumentation. On 3/15/17 an unknown red substance was found in the bottom of the tray. On 4/21/17 blood was found on top of spinal surgical instruments (rainbow curettes). On 1/23/18 a piece of bone was found in the bottom of the tray. d. Fifteen additional sterile processing department (SPD) employees were identified on the case report logs which identified similar findings of contamination, including bone, hair, blood, and cement. There was no documentation the SPD staff	H 503	Denominator = number of SPD staff required per the staffing plan, with a compliance goal of 90%. 5. Monitoring of vacancy rate monthly for the next year and quarterly thereafter. Numerator = number of filled positions; denominator = total number of open positions per staffing matrix, with a compliance goal of 90%. 6. Status of SPD staffing, per above, is reported to the Quality Council and Governing Board, monthly until the Governing Board determines staffing levels are not contributing to failures in surgical instrumentation decontamination and sterilization and that staffing has stabilized with a solid recruitment and retention program implemented. All data will be aggregated and reported monthly to the Quality Council, the OR Committee, Infection Prevention Committee and the Governing Board for a period of 4 months and quarterly thereafter until the Governing Board determines sustained compliance is achieved.	

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H 503	Continued From page 5 were retrained and had their competency evaluated to ensure contaminated instruments were completely cleaned, processed, and sterilized. e. On 2/27/18 at 10:27 a.m. an interview with SPD Manager #3 was conducted. Manager #3 stated "we are short staffed" and we're currently processing instruments for up to 50 cases a day which he considered to be "not safe." He stated "I don't have enough staff" and the sterile processing department was "severely short staffed." Manager #3 stated he was aware there were stil contaminated trays being delivered to the operating room recently after the sterilization process had been completed. He reported he did not have time to audit instruments after SPD staff completed the precleaning process and prior to the instruments being sterilized. He stated he had to wait for an incident report to be completed by OR staff to identify contaminated trays or instruments. Manager #3 stated he did not have time to audit SPD staff performance. Review of Manager #3's job description, signed 11/16/16, stated his duties included: identify staff development and training needs and provide coaching and training; evaluate and verify employee performance through the review of completed work assignments and work techniques; and investigate and work to resolve any safety and risk management issues. During a subsequent interview, on 2/28/18 at 10:07 a.m., Manager #3 again stated the SPD was too understaffed for him to be able to perform manager duties such as audits, monitoring occurrences, orienting new staff and conducting ongoing training and education for current staff. According to Manager #3 there was only one	H 503		

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H 503	Continued From page 6 staff member with case reports who received any corrective action. Manager #3 further stated none of the SPD staff members received any re-education or training on sterilization processes. f. During the interview, on 2/28/18 at 10:07 a.m., Manager #3 stated the sterile processing department became too busy to schedule normal staff in-services and all staff training and education was completed and documented during shift reports conducted at the beginning of each shift. On 2/28/18 at 3:17 p.m., the sterile processing department director, (Director #4), who had oversight of the SPD department and supervised Manager #3 was interviewed. Director #4 stated shift reports were detailed verbal team meeting discussions and all staff were expected to read and sign to ensure staff had received the education. However, review of the daily shift reports, dated 11/8/17 through 2/20/18, revealed multiple dates in which no shift reports were conducted or documented. Additionally, the shift reports reviewed showed no evidence of training or process changes implemented from contamination issues identified in the case reports. 2. The facility failed to ensure adequate staffing levels were maintained in the sterile processing department (SPD) for the number of surgical cases conducted. a. On 2/27/18 at 7:44 a.m., operating room (OR) #21was observed being set up for a surgical procedure for Patient #12. OR Manager #5 stated the procedure was delayed, awaiting instruments going through the sterilization process, because of lack of staffing in the sterile processing department.	H 503		

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H 503	Continued From page 7 b. On 2/27/18 at 10:27 a.m., an interview was conducted with SPD Manager #3, who was in charge of the daily operations in SPD. Manager #3 stated the SPD was "severely short staffed." Manager #3 reported the sterile process was unsafe due to the lack of staff. Manager #3 later stated, on 2/28/18 at 10:07 a.m., he was too understaffed to perform duties, to include: audits of the SPD process, monitor occurrences, orient new staff and provided ongoing training and education for current staff. Manager #3 provided a copy of an online listing of current job openings. Open positions were listed as one supervisor, five full-time sterile processing technicians, and one PRN (as needed) technician. On 2/28/18 at 9:35 a.m., an interview with Sterile Processing Department (SPD) Supervisor #2 was conducted. Supervisor #2 stated the sterile processing department was understaffed for the number of scheduled cases needing sterile surgical instruments. Supervisor #2 further stated the SPD was unable to catch up on the amount of backlogged instruments in the department needing to be sterilized and the instruments needed for ongoing cases. On 2/28/18 at 5:15 p.m., an interview with Sterile Processing Technician (SPT) #1 was conducted. SPT #1 stated the sterile processing department did not have enough staff and she felt she was unable to complete all of her assigned tasks within her shift. On 3/1/18 at 2:05 p.m., an interview with Chief Nursing Officer (CNO) #7 was conducted. CNO #7 reported she was aware of inadequate staffing in the sterile processing department for a couple of years, but the facility could not get a handle on staff turnover since April of 2017.	H 503		

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H 503	Continued From page 8 CNO #7 stated she reached out to the chief financial officer after an evaluation of the SPD was conducted and determined the SPD needed 7 positions filled. CNO #7 stated she had a discussion with the chief medical officer (CMO #6) and decided the 50 surgical cases performed on 2/27/18 (5 days after the start of the survey) were too much for the sterile processing department to keep up with and the decision was made to limit surgical cases to a "manageable workload" with their current resources. CNO #7 further stated this was the first time surgical cases were rescheduled due to SPD staffing issues. (Cross reference 0084)	H 503		
H 504	IV.5.102(1) Central Supplies: Sterilization Process Continuous supervision shall be maintained throughout receiving, cleaning, processing, sterilizing, and storing. A combination of controls or indicators shall be used to determine the effectiveness of the sterilization process. Bacteriological methods shall be used to evaluate the effectiveness of sterilization, by at least monthly cultures with records maintained. This REGULATION is not met as evidenced by: Based on observations, document review and interviews the facility failed to ensure surgical instruments were processed and available for scheduled surgeries, failed to follow manufacturer's instruction for proper maintenance of instrument washers, and failed to provide oversight of vendor representatives. This failure resulted in the routine use of	H 504	Tag H 504: Central Supplies, Sterilization Process Person Responsible: The Governing Body will have ultimate responsibility for all corrective actions and ongoing compliance associated with these	06/27/2018

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H 504	Continued From page 9 immediate use steam sterilization (IUSS) and the potential for transmission of healthcare acquired infections. Findings include: Facility Policy: The Sterile Processing Procedures policy read, use of immediate use steam sterilization (IUSS) will be kept to a minimum and only utilized in selected clinical situations when there is insufficient time to process by the preferred wrapped or container method. Vendors will have checked in at the designated vendor management system kiosk, donned appropriate ID and attire, prior to entering the Sterile Processing Department (SPD). The Surgical Attire policy read, clothing including long sleeved garments that cannot be covered by surgical attire shall not be worn in the restricted or semi-restricted areas. Non-scrubbed personnel should wear long-sleeved jackets in restricted areas. A clean, low lint surgical head cover that confines hair will be worn when in semi-restricted and restricted areas of the surgical suite. The Vendor Instrumentation policy read, all pans must be received by 2:00 p.m. the day prior to surgery. Monday cases need to be received by 2:00 p.m. the Friday before surgery is scheduled. The Universal Protocol policy read, the elements on the Surgical Safety Checklist were selected to ensure that additional elements considered essential to patient safety were consistently addressed prior to procedures. The standardized list will include verification during the time out that devices or special equipment are available.	H 504	requirements, however the Chief Nursing Officer) CNO and Chief Medical Officer (CMO) provide direct oversight. The CNO and CMO collaborated regarding when the sterilization process affected the availability of sterile instruments for scheduled surgeries. The Perioperative Services Director has direct oversight of the Sterile Processing Manager, who is responsible for the operational oversight of the SPD. Actions: 1. The Governing Board has full responsibility for determining, implementing and monitoring the Hospital's total operations and compliance with its policies and procedures. 2. The Governing Board was informed of the outcome of accreditation surveys occurring 2/20/18 forward, via phone calls and meetings. The Governing Board held regular meetings and conference calls, late February forward, to discuss the survey findings and the plans of correction. 3. The Governing Board meets monthly and as necessary to discuss overall operational and patient care issues, related but not limited to, effectiveness of sterilization. Hospital leadership worked closely with Centura corporate leadership to assist with correction of survey findings and implementation of processes to sustain compliance. 4. Point-of-use pre-cleaning competencies began for all SPD and OR staffs on 2/22/18, including condition that instruments should arrive in SPD, and without gross contamination. 5. SPD staff trained on Stop-the-Line	

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H 504	Continued From page 10 References: According to The Association of Perioperative Registered Nurses (AORN), Guidelines for Perioperative Practice, 2017: Recommendation VII (Page 871), IUSS may be associated with an increased risk of infection to patients and should be kept to a minimum. According to the Reliance Synergy Washer/Disinfector Operation Manual, maintenance procedures described in this section must be performed as required at the suggested frequency. Weekly routine cleaning procedures include cleaning the wash chamber rotary spray arm assembly, removing and cleaning the spray arms, cleaning the rotary spray arm assembly on accessories, the door gasket, front panel, and the display. It is the responsibility of the customer to perform the decontamination of their unit once per week as instructed. Decontaminate and descale the chamber using the DECONTAM cycle expressly designed for this purpose. 1. The facility failed to ensure surgical instruments needed for surgeries were sterilized and available for use at the scheduled start time of patients' surgeries. a. On 2/27/18, a surgical case tracer scheduled for 7:30 a.m. was observed. At 6:55 a.m., Certified Surgical Technician (CST) #10 stated she went to the sterile processing department (SPD) prior to setting up for the case and instruments required for the current case were still cooling. CST #10 stated she frequently had to wait for instruments to be delivered from the sterile processing department (SPD) at the start of the day. At 7:34 a.m., OR Manager #5 called the SPD to	H 504	process, 3/7/18: any cart with visible gross bioburden is immediately rejected by SPD and leadership/ supervisor is notified immediately. 6. Requirement to follow IFUs when decontaminating/cleaning instruments was addressed by the contract IP, working with observed SPTs, reminding them of the requirement to follow the IFU for decontamination of each instrument. 7. Gaps in education and documented sterile processing competencies were identified. To address these gaps, a surgical medical supply company, knowledgeable in surgical instrumentation cleaning, disinfection and sterilization, was contracted to provide retraining/re-validation of staff competence for all components of the cleaning/ decontamination and sterilization processes, 2/28/18. Training included didactic and demonstration components, completed 3/6/18. 8. A priority list of instruments/equipment needed next/same day, was developed to be followed by staff, and was mounted on a designated cart in Sterile Processing Department (SPD). Staff review items on priority list, cross off and initial for completed task to inform other staff and reinforce the work was completed 4/20/18. Daily huddles with OR Assistant Nurse Managers are held to review the next day's priority list; this list given to SPD daily – 4/20/18. 9. A priority board was designed and mounted on 4/18/18 in the decontamination area to assist staff to prioritize changing needs related to instrument cleaning. Education to the	

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H 504	Continued From page 11 ascertain when the instruments would be ready. Manager #5 stated the staff member from the SPD she spoke with reported the instruments would be ready for delivery to the OR suite in 10 to 15 minutes. At 7:50 a.m., 20 minutes after the scheduled surgery start time, several surgical instrument trays arrived to the OR suite. At 9:30 a.m., a time out occurred with Vendor #15 and all staff present in the OR suite. The entire team participated, including Vendor #15, with no equipment comments or concerns identified. The time out included verbal verification that all sterilized instruments required for the case were present. At 9:36 a.m., Physician #17 made the first incision. At 9:44 a.m., Vendor #15 brought another tray of surgical instruments into the OR suite and stated he had to wait for them to cool prior to bringing them into the operating room. When asked about the late tray, Vendor #15 stated he should have spoken up during the timeout to notify the team that the tray was unavailable and was still cooling in the SPD. At 9:44 a.m., OR Manager #5 was interviewed and stated the facility's expectation was for all needed surgical trays to be sterilized and available prior to the patient entering the OR suite. Manager #5 further stated she would have expected a discussion from Vendor #15 about the delay of the surgical tray arriving to the OR suite during the time out. On 2/27/18 at 4:05 p.m., CST #10 was interviewed. CST #10 stated she thought all of the necessary surgical instruments were in the OR suite and available when the OR team verified all instrumentation was in the room during the time out. CST #10 further stated all of the instrumentation needed for the procedure should have been in the room prior to the incision. CST #10 stated that case carts were not always stocked properly because sterile	H 504	board was completed 4/25/18 10. A review of instrument washer maintenance requirements (review of IFU), was performed by the Director of Biomedical Engineering on 4/6/18. 11 The manufacturer of the instrument washer, Steris, came onsite to restore the instrument washers to operable condition on 4/6/18. SPD staff was retrained on the descaling process on 4/8/18. 12. Competencies related to ongoing washer descaling completed and documented by 6/8/18. 13. The frequency of descaling of washers was increased to at least 3X/week, starting 4/7/18. The descaling of the washers is assigned to the SPD lead/Manager. Completion of descaling is documented on department log for each washer. Visual inspection of the washer heater coils is completed weekly by the SPD Manager or designee, starting 4/9/18. The inspection is documented on department log for each washer. 14. When discoloration on instrumentation is observed, loads (random packs and cassettes) from the day the discoloration is noted will be visually inspected. Determine if discoloration is an isolated problem or larger issue. If isolated, instruments are reprocessed. Instruments may be sent to the surgical medical supply company for refurbishing or to be retired at end-of-life. 15. If larger issue, the washer involved is shut down until the source of the problem is determined. Episodes of instrument discoloration or staining are reported to	

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H 504	Continued From page 12 instruments were not ready when they were needed. b. On 2/27/18 at 7:50 a.m., an observation in the sterile OR corridor revealed an oculoplasty set (instrumentation used for surgical procedures involving structures around the eyes) was undergoing an IUSS cycle in autoclave #9. Further observation in the sterile operating room corridor revealed an ear, nose and throat drill set undergoing an IUSS cycle in autoclave #2 for the same patient awaiting the oculoplasty set. Registered Nurse (RN) #11 removed the tray from autoclave #2 and stated the tray was not ready when the surgery was scheduled to start which required the use of IUSS for those instruments. Scrub Technician (ST) #12 stated the instrument tray required IUSS because it was not sterile at the beginning of the day. During the observation in the sterile OR corridor, Manager #5 confirmed the reason the oculoplasty tray required IUSS was it was not sterilized by the SPD in time for the surgery start time. c. On 2/28/18 at 11:54 a.m., an interview with Clinical Nursing Specialist (CNS) #8 was conducted. CNS #8 stated SPD did not have enough "man power" to meet the work demand resulting in instruments processed utilizing IUSS. CNS #8 continued by stating if there was not enough SPD staff available to meet the scheduled work load, they would always be behind in sterilizing surgical instruments. CNS #8 stated the main reason for the usage of IUSS was due to the inability to complete a full standard sterilization cycle in the SPD in time for the surgical case to begin. If surgical instruments were not sterilized by the start time of the surgical case, CNS #8 explained staff would at times utilize IUSS and document the reason for IUSS as the "item was unsterile."	H 504	the SPD Manager and Director of Perioperative Services for immediate action to identify the problem area. 16. Episodes of instrument discoloration or staining are documented and monitored in the occurrence reporting system, where they will be tracked and trended. Outcomes of the Perioperative Director and SPD leadership's response and identified reason for the discoloration/staining are documented in the occurrence reporting system. Compliance and Monitoring: 1. Monitoring of IUSS rate and reasons conducted monthly. Numerator = number of instruments/instrument sets receiving IUSS; denominator = number of surgical cases with an IUSS target rate of 5% due to inadequately sterilized instruments (versus dropped or inadvertently contaminated during procedures). 2. Checklist procedure requiring double-check sign-off of scrub tech and other OR designee to ensure point-of-use pre-cleaning and removal of gross bioburden and spraying of instruments with enzymatic instrument spray. A final check at point of departure from OR to SPD is performed to ensure lack of gross bioburden and presence of enzymatic spray. Fall-outs are entered into the occurrence reporting system for review and trending. 100% of carts are signed off at point-of-use and again at point of departure from the OR and prior to transport to SPD. Carts are monitored for at least 60 days, beginning 2/21/18. When 100% compliance is achieved for 60 days, monitoring will transition to a random audit of 75 case carts per week for one month. When 100% compliance	

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H 504	Continued From page 13 CNS #8 further stated IUSS was not an acceptable practice and should only be used in an emergency. d. A review of the IUSS logs, from 1/1/18 to 2/28/18, revealed IUSS was utilized on surgical instruments 60 times. During this timeframe, 21 instances had the reason documented for IUSS as the item was unsterile. e. On 2/28/18 at 3:17 p.m., an interview with SPD Director #4 was conducted. Director #4 stated using IUSS to sterilize surgical instruments was not ideal due to the potential contamination of surgical trays when transporting them from the autoclave to the operating room table. Director #4 stated IUSS could also be associated with infection if there was bioburden left on instruments. Director #4 added that she had discussed the need to have SPD staff participate in a flexible schedule in order to finish processing instruments from the prior day, keep up with the instruments for the current day and prepare for the next day. However, Director #4 explained there had been no changes in SPD staff scheduling implemented at the time of the survey. f. On 3/1/18 at 11:00 a.m., an interview was conducted with Infection Prevention Registered Nurse (IP RN) #9. IP RN #9 confirmed the facility followed AORN guidelines in the perioperative area, which included the minimized use of IUSS. IP RN #9 stated the risks involved with using IUSS, instead of the standard sterilization process would be contamination and infection. IP RN #9 stated IUSS should only be used in emergency situations. g. On 3/1/18 at 2:05 p.m., an interview with the chief nursing officer (CNO #7) was conducted.	H 504	is sustained for one month, an audit of 75 random carts per month will occur for one month. 3. Monitoring of case start delays and reasons. Numerator - # of case start delays due to instrumentation; denominator = number of cases. Target is 0% delays due to instrumentation. 4. Monitoring of failures in proper decontamination and/or sterilization on an as occurrence basis to ensure remedial action is taken. Numerator = number of reported decontamination/sterilization failures monthly; Denominator = number of surgical cases performed monthly with a goal of 0% failure rate. 5. Incidents of instrument discoloration or staining are entered in the occurrence reporting system where they are tracked and trended. Instances of this nature are reported in trended format monthly to the Quality Council, OR Committee, and Governing Board. Target for discoloration and staining on instruments, due to reprocessing failures, is 0%. 6. Documentation of descaling and visual inspection of washer coils will be monitored by the Safety Manager. Department logs are monitored for presence of documentation of checks monthly with a goal of 100% compliance for coil inspection and log completion. Compliance will be reported monthly to the Quality Council, OR Committee and Governing Board for 4 months and quarterly thereafter until Governance determines sustained compliance has been achieved.	

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H 504	Continued From page 14 CNO #7 stated issues with staffing, leadership turnover and leadership oversight were all contributing factors for the routine use of IUSS. CNO #7 stated the issues of staffing and leadership oversight were due to leadership turnover and had been present for two years. 2. The facility failed to ensure instrument washer machines were consistently maintained in accordance with manufacturer's instructions. a. The Daily/Weekly Checklists utilized in the SPD from 1/1/17 to 4/5/18 were requested for review; however, the manager of regulatory programs (Manager #24) stated she was unable to locate the Checklists from 1/1/17 to 7/1/17 (25 weeks). In addition, there were no checklists from 7/30/17 to 9/4/17 (over 8 weeks), 10/29/17 to 2/3/18 (almost 14 weeks), and 4/1/18 to 4/5/18. The Checklists provided consisted of several tasks intended to be completed on a daily or weekly basis by SPD staff. There was no documentation of a descaling process (removal of hard deposits formed by chemicals in water) completed on the instrument washers from 10/15/17 to 10/27/17 and 2/24/18 to 3/9/18. This was in contrast to the instrument washer operation manual which stated it was the responsibility of the customer to perform the decontamination and descaling process on a weekly basis. 3. The facility failed to provide oversight and ensure vendor loaned surgical instruments were delivered to the facility to be processed by the time required by facility policy. a. On 2/27/18, a surgical case tracer scheduled for 7:30 a.m. was observed. At 7:50 a.m., 20 minutes after the scheduled surgery start time, several vendor supplied surgical instrument trays arrived to the OR suite.	H 504		

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H 504	Continued From page 15 At 9:36 a.m., Physician #17 made the first incision. At 9:44 a.m., Vendor #15 brought in another tray of vendor surgical instruments into the OR suite and stated he had to wait for them to cool prior to bringing them into the operating room. At 9:44 a.m., OR Manager #5 was interviewed and stated the facility's expectation was for all needed surgical trays to be sterilized and available prior to the patient entering the OR suite. On 2/27/18 at 10:27 a.m., an interview with SPD Director #4 was conducted. Director #4 stated vendors were expected to bring surgical instruments to the SPD no later than 2:00 p.m. the day prior to the surgery in which they were intended to be used. Director #4 stated that all vendors were tracked when entering and exiting the facility through a computer system called Rep Tracks. Director #4 stated she was unaware of any auditing done of vendor's work and that this was something the SPD could improve on. A review of Rep Tracks was conducted and revealed Vendor #15 delivered instruments for Patient #12's surgery on 2/26/18 at 3:16 p.m. This was approximately 75 minutes after the 2:00 p.m. expectation for vendors to deliver instruments to the sterile processing department prior to procedures to allow for enough time for the standard sterilization process. 4. The facility failed to ensure outside vendors followed facility policy regarding required attire ir the sterile processing department. a. On 2/27/18 at 10:05 a.m., a tour of the sterile processing department was conducted with SPD Manager #3. Vendor #16 was observed setting up clean instruments in trays to be	H 504		

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H 504	Continued From page 16 sterilized. Vendor #16 was not wearing a surgical hair cover and was wearing a personal long sleeve shirt under a surgical scrub top without a surgical scrub jacket. Vendor #16 left the room briefly and returned with a surgical hair cover on and a surgical scrub jacket on over his long sleeve shirt and the scrub shirt. b. On 2/27/18 at 10:27 a.m., an interview with SPD Director #4 was conducted. Director #4 stated the expectation was for vendors to wear surgical scrubs including a jacket, shoe covers and hair covers while processing instruments. Director #4 stated any vendors not complying with those requirements were expected to be escorted out of the area immediately.	H 504		
H 606	IV.6.102(2) Governing Board: Responsibility [The governing board shall:] be responsible for all the functions performed within the hospital. This REGULATION is not met as evidenced by: Based on observations, interviews and record review the governing body failed to provide oversight of services provided within the hospital to ensure they were provided in a safe manner and in accordance with professional standards in the areas of surgical services, infection control, quality assessment and performance improvement and contracted services. Specifically the facility failed to ensure surgical services were provided in accordance with established standards, failed to provide oversight of the sterile processing department staff, and failed to identify, track and trend surgical site infections. These failures resulted in the ongoing prevalence of incidents where surgical instruments were not completely	H 606	Tag H 606: Governing Board Responsibiltiy Person Responsible: The Governing Board will have ultimate responsibility for all corrective actions and ongoing compliance associated with these requirements, however the Chief Nursing Officer) CNO and Chief Medical Officer (CMO) provide direct oversight. The CNO and CMO collaborated in discussions with the Governing Body, regarding provision of services, including contracted services, in a safe manner and	06/27/2018

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H 606	Continued From page 17 cleaned and sterilized for use in surgical cases, the routine utilization of immediate use steam sterilization (IUSS), and surgical site infections not being investigated and reported to identify potential trends and areas for improvement. Findings include: Facility policy: The Sterile Processing Procedures policy read, use of immediate use steam sterilization (IUSS) will be kept to a minimum and only utilized in selected clinical situations when there is insufficient time to process by the preferred wrapped or container method. Vendors will have checked in at the designated vendor management system kiosk, donned appropriate ID and attire, prior to entering the Sterile Processing Department (SPD). The Surgical Attire policy read, clothing including long sleeved garments that cannot be covered by surgical attire shall not be worn in the restricted or semi-restricted areas. Non-scrubbed personnel should wear long-sleeved jackets in restricted areas. A clean, low lint surgical head cover that confines hair will be worn when in semi-restricted and restricted areas of the surgical suite. The Vendor Instrumentation policy read, all pans must be received by 2:00 p.m. the day prior to surgery. Monday cases need to be received by 2:00 p.m. the Friday before surgery is scheduled. References: According to the Role and Responsibility Matrix, the facility's board is fully accountable for implementing, monitoring and evaluating the quality of operating entity contracted services	H 606	in accordance with professional standards for surgical services and infection control. Actions: 1. The Governing Board has full responsibility for determining, implementing and monitoring the Hospital's total operations and compliance with its policies and procedures. 2. The Governing Board was informed of the outcome of accreditation surveys occurring 2/20/18 forward, via phone calls and meetings. The Governing Board held regular meetings and conference calls late February forward, to discuss the survey findings and the plans of correction. 3. The Governing Board meets monthly, and as necessary, to discuss overall operational and patient care issues, related but not limited to, effectiveness sterilization and infection control program and practices. Hospital leadership worked closely with Centura corporate leadership to assist with correction of survey findings and implementation of processes to sustain compliance. 4. The Governing Board requires monthly reports of data regarding improvements and actions taken related to surgical site infections (SSI) and Sterile Processing Department (SPD) processes, including immediate use steam sterilization (IUSS). Process and outcome data are required to permit the Governing Board to make informed decisions related to actions needed for improvements and to understand rate, magnitude and variability of process improvements. The Governing Board also oversees and directs the frequency and detail of	

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H 606	Continued From page 18 and that any required improvements are integrated with the operating entity's quality program. According to the Quality Assessment, Patient Safety and Performance Improvement Plan, dated 11/16/17, the facility will utilize information from risk assessments and ongoing data analysis to make changes that will improve quality, performance and patient safety and reduce the likelihood and risk of sentinel events and other adverse events. According to The Association of Perioperative Registered Nurses (AORN), Guidelines for Perioperative Practice, 2017: Recommendation VII (Page 871), IUSS may be associated with an increased risk of infection to patients and should be kept to a minimum. 1. The facility failed to provide oversight of the sterile processing department (SPD) staff to ensure equipment was completely cleaned, processed and sterilized appropriately by trained and qualified personnel. a. A review of the Sterile Processing Department (SPD) Case Reports log from 1/19/17 to 2/9/18 was conducted. During an interview with Clinical Nurse Specialist (CNS) #8, on 2/28/18 at 1:51 p.m., she stated the log contained data from SPD case reports which were completed by operating room staff who discovered an issue after the tray was delivered to the operating room (OR) suite. According to CNS #8 the reports were sent down to SPD and the SPD manager created the log. Review of the Case Report log revealed 17 of 22 SPD staff members had one or more incidents of documented contamination after the sterilization process which included bone, hair, blood, and cement. As example,	H 606	improvement activities. 5. A review of Governing Board Bylaws and Responsibility Matrix to ensure Board understanding of roles and responsibilities at the 5/24/18 Board meeting. 6. The Board was educated per the Matrix, that it is their responsibility to ensure issues with contracted services are monitored through the QAPI program. Expectations of staff qualifications are outlined in contractual agreements between providers and Porter Adventist Hospital and/or Centura. These include an expectation that providers are compliant with state and federal law, regulation and accrediting body requirements. 7. The Governing Board's overall evaluation of contracted services was reviewed at the 5/24/18 meeting of the Governing Board and will be reviewed at least annually thereafter, per policy. Ongoing review of contracted providers' performance is reviewed as a component of indicator monitoring, as scheduled, through the hospital's QAPI program when indicated. 8. The Governing Board evaluates contracted providers, including contracted providers supplying personnel for compliance with the performance expectations of the contract. 9. The Governing Board evaluates contracted providers, including those supplying personnel, for compliance with performance expectations of the contract. As part of the QAPI Calendar of Reporting, contract service lists will include an evaluation of their performance expectations. The Governing Board's	

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H 606	Continued From page 19 Sterile Processing Technician (SPT) #13 had a total of 63 documented incidents involving concerns with trays processed from 1/19/17 to 2/9/18. From 1/19/17 to 3/28/17, SPT #13 had 17 reported incidents. Five of the 17, were contamination errors within a surgical tray (pan). On 1/24/17 chunks of bone found inside of the pan. On 2/16/17 cement was found on the instrumentation. On 3/8/17 visible bone and blood were found in the pan. On 3/22/17 bioburden was found while in a surgical case. Subsequent to these incidents, on 3/28/17, SPT #13 received a written corrective action. Review of the corrective action revealed, a written warning was issued for SPD#13's failure to meet the performance expectations of his position. Specifically, on 3/23/17 dirty Kerrisons (spinal surgical instruments) were found in an instrument set during a surgical case. The form noted on 3/7/17 the employee had received a verbal warning regarding dirty instrumentation in instrument sets. After the corrective action SPT #13 had 11 additional case reports that involved contaminated trays. As example, On 6/29/17 OR staff documented a dead bug was found in the surgical tray. On 8/1/17 and 8/9/17 cement was found on the cement gun (surgical instrumentation). On 8/28/17 crusty blood or tissue was found on a surgical instrument. On 9/6/17 cement was found on an instrument. On 11/22/17 blood from a previous surgical case was found on a piece of an instrument.	H 606	overall evaluation of contracted services was reviewed at the 5/24/18 meeting. 10. Contract with a surgical medical supply company, knowledgeable in surgical instrumentation cleaning, disinfection and sterilization, to provide contracted SPD techs was modified on 4/17/18, to remove requirement for certification of techs. 11. When remedial actions for SPD contracted provider staff members are not effective, the contracted staff member will be requested for termination. Any instances of termination for performance are a component of the contact evaluation. 12. Contracted SPD tech new hire files will be reviewed monthly for progress with completion of initial, unit-based competencies. Contract SPD techs will not be permitted to perform tasks independently until they are signed off by a trained and competent lead tech. 13. Point-of-use pre-cleaning competencies began for all SPD and OR staffs on 2/22/18, including condition that instruments should arrive in SPD, without gross contamination. 14. SPD staff trained on Stop-the-Line process, 3/7/18: any cart with visible gross bioburden is immediately rejected by SPD and leadership/ supervisor is notified immediately. 15. Requirement to follow IFUs when decontaminating/cleaning instruments was addressed by the contract consultant IP, working with observed SPTs, reminding them of the requirement to	

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H 606	Continued From page 20 On 3/1/18 at 7:06 a.m., an interview with SPT # 13 was conducted. SPT #13 stated SPD staff were currently recleaning, repackaging, and resterilizing every instrument in the department due to a recent incident in which surgical instruments were delivered to the OR suite which were not "up to standards" due to the "amount of bioburden" on them. b. Continued review of the Case Report log revealed SPT #18 had 12 incidents from 1/19/17 to 2/9/18 of documented contamination after the sterilization process; such as cement, bone and hair found on instruments or inside the tray. Specifically: On 1/19/17 two separate documented incidents of cement found on instruments. On 2/22/17 an incident of blood on a knife handle was noted. On 5/30/17 bone was found in the bottom of a tray. On 6/1/17 an instrument was found to have dried blood on it. On 6/28/17 black residue was found on an instrument. On 7/19/17, 8/9/17 and again on 8/22/17, cement was found left on instrumentation, all of which were found by OR staff in the OR suite. On 12/5/17 a foreign object (white lock) was documented as being found in a surgical tray. c. According to the case reports, from 1/25/17 to 1/23/18, SPT #19 had 10 incidents of contamination errors including blood, bone and rust found on the instruments and inside surgical trays. As example, On 1/25/17 an instrument was noted as clogged with the previous patients blood. On 1/26/17 blood was found on a drill bit. On 2/16/17 and 3/1/17 cement was found on instrumentation.	H 606	follow the IFU for decontamination of each instrument. 16. Gaps in education and documented sterile processing competencies were identified. To address these gaps, a surgical medical supply company, knowledgeable in surgical instrumentation cleaning, disinfection and sterilization, was contracted to provide retraining/re-validation of staff competence for all components of the cleaning/ decontamination and sterilization processes, 2/28/18. Training included didactic and demonstration components, completed 3/6/18. 17. A priority list of instruments/equipment needed next/same day, was developed to be followed by staff, and was mounted on a designated cart in Sterile Processing Department (SPD). Staff review items on priority list, cross off and initial for completed task to inform other staff and reinforce the work was completed - 4/20/18. Daily huddles with OR Assistant Nurse Managers are held to review the next day's priority list; this list given to SPD daily – 4/20/18. 18. A priority board was designed and mounted on 4/18/18 in the decontamination area to assist staff to prioritize changing needs related to instrument cleaning. Education to the board was completed 4/25/18 19. Immediate SPD staffing plan developed to address variances in staffing levels, immediate staffing needs and considered skill sets required, surgical volume and instrument inventory, developed to staff SPD, 2/23/18. Staffing levels reviewed, new SPD staffing matrix	

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H 606	Continued From page 21 On 3/15/17 an unknown red substance was found in the bottom of the tray. On 4/21/17 blood was found on top of spinal surgical instruments (rainbow curettes). On 1/23/18 a piece of bone was found in the bottom of the tray. d. Fifteen additional sterile processing department (SPD) employees were identified on the case report logs which identified similar findings of contamination, including bone, hair, blood, and cement. e. On 2/27/18 at 10:27 a.m., an interview with SPD Manager #3 was conducted. Manager #3 stated "we are short staffed" and we're currently processing instruments for up to 50 cases a day which he considered to be "not safe." He stated "I don't have enough staff" and the sterile processing department was "severely short staffed." Manager #3 stated he was aware there were stil contaminated trays being delivered to the operating room recently after the sterilization process had been completed. He reported he did not have time to audit instruments after SPD staff completed the precleaning process and prior to the instruments being sterilized. He stated he had to wait for an incident report to be completed by OR staff to identify contaminated trays or instruments. Manager #3 stated he did not have time to audit SPD staff performance. During a subsequent interview, on 2/28/18 at 10:07 a.m., Manager #3 again stated the SPD was too understaffed for him to be able to perform manager duties such as audits, monitoring occurrences, orienting new staff and conducting ongoing training and education for current staff. 2. The facility failed to ensure adequate staffing levels were maintained in the sterile processing	H 606	developed with consideration of peak volume times, staff skill sets and instrument availability. Staffing increased by 7 FTE positions, 2/28/18. Analyzed and balanced staffing across shifts in accordance with work volume. This includes at least 2 individuals staffed in decontamination to handle caseload, starting 4/13/18. Balanced, final staffing schedule created 4/20/18, including off-shift coverage. This “balanced” schedule is intended to smooth staffing over all shifts and days of the week, in response to case volumes. 20. Emergency shift bonus pay instituted on 2/21/18 to assist with immediate staffing requirements. Meetings to identify Corporate resources to assist with immediate response, 2/22-23/18. 21. Ongoing collaboration continues with Centura, the hospital’s corporate human resources department, to actively recruit and identify qualified SPD technicians. One SPD technician was hired as of 4/24/18. 2 additional fulltime SPD technicians will begin on 5/14/18. New technicians will complete orientation in 90-120 days, per policy. 22. Contracted agency supplies experienced and competent SPD technicians; 8 open positions filled. Travelers began 3/5/18 and are currently contracted through 7/12/18. 23. Experienced SPD Leads/Supervisors were identified and scheduled, starting 4/13/18, to provide 24/7 oversight of decontamination and sterilization processes. 24. An experienced Interim Perioperative	

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H 606	Continued From page 22 department (SPD) for the number of surgical cases conducted. a. On 2/27/18 at 7:44 a.m., operating room (OR) #21 was observed being set up for a surgical procedure for Patient #12. OR Manager #5 stated the procedure was delayed, awaiting instruments going through the sterilization process, because of lack of staffing in the sterile processing department. b. On 2/27/18 at 10:27 a.m., an interview was conducted with SPD Manager #3, who was in charge of the daily operations of SPD. Manager #3 stated the SPD was "severely short staffed." Manager #3 reported the sterile process was unsafe due to the lack of staff. Manager #3 later stated, on 2/28/18 at 10:07 a.m., he was too understaffed to perform duties to include audits of the SPD process, monitor occurrences, orient new staff and provided ongoing training and education for current staff. On 2/28/18 at 9:35 a.m., an interview with sterile processing department (SPD) Supervisor #2 was conducted. Supervisor #2 stated the sterile processing department was understaffed for the number of scheduled cases needing sterile surgical instruments. Supervisor #2 further stated the SPD was unable to catch up on the amount of backlogged instruments in the department needing to be sterilized and the instruments needed for ongoing cases. On 2/28/18 at 5:15 p.m., an interview with Sterile Processing Technician (SPT) #1 was conducted. SPT #1 stated the sterile processing department did not have enough staff and she felt she was unable to complete all of her assigned tasks within her shift. On 3/1/18 at 2:05 p.m., an interview with Chief Nursing Officer (CNO) #7 was conducted. CNO #7 reported she was aware of inadequate	H 606	Director was identified on 3/4/18, to replace resigning Director 3/23/18. Interim dyad leadership structure created. One leader specifically focuses on the operational oversight and accountability of the SPD processes and staffing to ensure that sterile instruments are ready and available for scheduled cases. The other leader focuses primarily on OR processes and operations. Position for permanent Perioperative Director and posted 3/19/18. 25. The Perioperative Services Director notifies senior leadership when insufficient SPD staffing may result in unavailability of instrumentation for scheduled procedures/ surgeries. The OR schedule may be adjusted, as needed - Ongoing. 26. An experienced Interim SPD Manager was hired through contracted agency, starting 4/10/18, to manage staffing and oversee sterilization processes. The Interim SPD Manager reviews all occurrences and ensures staff is coached/trained and that corrective action is taken when appropriate. The Interim SPD Manager reports staffing issues that impact ability to process instrumentation needs, to the Perioperative Services Director. 27. Position for SPD Educator posted 3/19/18 and an interim educator was hired, starting 5/29/18. The SPD Educator assists with ongoing continuing education and competency assessment of SPD staff. Compliance and Monitoring: 1. Monitoring of IUSS rate and reasons conducted monthly. Numerator = number of instruments/instrument sets receiving	

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H 606	Continued From page 23 staffing in the sterile processing department for a couple of years, but the facility could not get a handle on staff turnover since April of 2017. CNO #7 stated she reached out to the chief financial officer after an evaluation of the SPD was conducted and determined the SPD needed 7 positions filled. CNO #7 stated she had a discussion with the chief medical officer (CMO #6) and decided the 50 surgical cases performed on 2/27/18 (5 days after the start of the survey) were too much for the sterile processing department to keep up with and the decision was made to limit surgical cases to a "manageable workload" with their current resources. CNO #7 further stated this was the first time surgical cases were rescheduled due to SPD staffing issues. 3. The facility failed to ensure surgical instruments needed for surgeries were sterilized and available for use at the scheduled start time of patients' surgeries. a. On 2/27/18, a surgical case tracer scheduled for 7:30 a.m. was observed. At 6:55 a.m., Certified Surgical Technician (CST) #10 stated she went to the sterile processing department (SPD) prior to setting up for the case and instruments required for the current case were still cooling. CST #10 stated she frequently had to wait for instruments to be delivered from the SPD at the start of the day. At 7:34 a.m., OR Manager #5 called the SPD to ascertain when the instruments would be ready. Manager #5 stated the staff member from the SPD she spoke with reported the instruments would be ready for delivery to the OR suite in 10 to 15 minutes. At 7:50 a.m., 20 minutes after the scheduled surgery start time, several surgical instrument trays arrived to the OR suite.	H 606	IUSS; denominator = number of surgical cases with an IUSS target rate of 5% due to inadequately sterilized instruments (versus dropped or inadvertently contaminated during procedures) 2. Checklist procedure requiring double-check sign-off of scrub tech and other OR designee to ensure point-of-use pre-cleaning and removal of gross bioburden and spraying of instruments with enzymatic instrument spray. A final check at point of departure from OR to SPD is performed to ensure lack of gross bioburden and presence of enzymatic spray. Fall-outs are entered into the occurrence reporting system for review and trending. 100% of carts are signed off at point-of-use and again at point of departure from the OR and prior to transport to SPD. Carts are monitored for at least 60 days, beginning 2/21/18. When 100% compliance is achieved for 60 days, monitoring will transition to a random audit of 75 case carts per week for one month. When 100% compliance is sustained for one month, an audit of 75 random carts per month will occur for one month. 3. Monitoring of case start delays and reasons. Numerator - # of case start delays due to instrumentation; denominator = number of cases. Target is 0% delays due to instrumentation. 4. Monitoring of failures in proper decontamination and/or sterilization on an as occurrence basis to ensure remedial action is taken. Numerator = number of reported decontamination/sterilization failures monthly; Denominator = number of surgical cases performed monthly with a goal of 0% failure rate.	

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H 606	Continued From page 24 At 9:30 a.m., a time out occurred with all staff present in the OR suite and Vendor #15. The entire team participated, including Vendor #15, with no equipment comments or concerns identified. The time out included verbal verification that all sterilized instruments required for the case were present. At 9:36 a.m., Physician #17 made the first incision. At 9:44 a.m., Vendor #15 brought another tray of surgical instruments into the OR suite and stated he had to wait for them to cool prior to bringing them into the operating room. When asked about the late tray, Vendor #15 stated he should have spoken up during the timeout to notify the team that the tray was unavailable and was still cooling in the SPD. At 9:44 a.m., OR Manager #5 was interviewed and stated the facility's expectation was for all needed surgical trays to be sterilized and available prior to the patient entering the OR suite. Manager #5 further stated she would have expected a discussion from Vendor #15 about the delay of the surgical tray arriving to the OR suite during the time out. On 2/27/18 at 4:05 p.m., CST #10 was interviewed. CST #10 stated she thought all of the necessary surgical instruments were in the OR suite and available when the OR team verified all instrumentation was in the room during the time out. CST #10 further stated all of the instrumentation needed for the procedure should have been in the room prior to the incision. CST #10 stated that case carts were not always stocked properly because sterile instruments were not ready when they were needed. b. On 2/27/18 at 7:50 a.m., an observation in the sterile OR corridor revealed an oculoplasty set (instrumentation used for surgical procedures involving structures around the eyes) was undergoing an immediate use steam sterilization	H 606	5. Monitoring of completion of counseling/corrective action in relationship to each identified failure. Numerator = number of corrective actions documented related to failures monthly; Denominator = number of occurrence reports related to SPD process fall-out occurrences monthly, with a goal of 100% compliance. Ongoing retraining and competency completion rate, for any SPD and OR staff not included in the initial training, is 100%. 6. Rate of completion of new-hire competencies by 90-120 days, per policy, for associates starting in February 2018, forward. This will be monitored monthly for 4 months and quarterly thereafter. 7. Daily monitoring of available SPD staff matching the staffing plan. Numerator = number of available SPD staff; Denominator = number of SPD staff required per the staffing plan, with a compliance goal of 90%. 8. Monitoring of vacancy rate monthly for the next year and quarterly thereafter. Numerator = number of filled positions; denominator = total number of open positions per staffing matrix, with a compliance goal of 90%. 9. Status of SPD staffing, per above, is reported to the Quality Council and Governing Board, monthly until Governance determines staffing levels are not contributing to failures in surgical instrumentation decontamination and sterilization and that staffing has stabilized with a solid recruitment and retention program implemented. All data will be aggregated and reported monthly to the Quality Council, the OR Committee,	

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H 606	Continued From page 25 (IUSS) cycle in autoclave #9. Further observation in the sterile operating room corridor revealed an ear, nose and throat drill set undergoing an IUSS cycle in autoclave #2 for the same patient awaiting the oculoplasty set. Registered Nurse (RN) #11 removed the tray from autoclave #2 and stated the tray of instruments was not ready when the surgery was scheduled to start which required the use of IUSS for those instruments. Scrub Technician (ST) #12 verified the instrument tray required IUSS because it was not sterile at the beginning of the day. During the observation in the sterile OR corridor, Manager #5 confirmed the reason the oculoplasty tray required IUSS was it was not sterilized by the SPD in time for the surgery start time. c. On 2/28/18 at 11:54 a.m., an interview with Clinical Nursing Specialist (CNS) #8 was conducted. CNS #8 stated the SPD did not have enough "man power" to meet the work demand resulting in instruments processed utilizing IUSS. CNS #8 continued by stating if there was not enough SPD staff available to meet the scheduled work load, the department would always be behind in sterilizing surgical instruments. CNS #8 stated the main reason for the usage of IUSS was due to the inability to complete a full standard sterilization cycle in the SPD in time for the surgical case to begin. If surgical instruments were not sterilized by the start time of the surgical case, CNS #8 explained the instruments would at times utilize IUSS and staff would document the reason for utilizing IUSS as the "item was unsterile." CNS #8 further stated IUSS was not an acceptable practice and should only be used in an emergency. d. A review of the IUSS logs, from 1/1/18 to	H 606	Infection Prevention Committee and the Governing Board for a period of 4 months and quarterly thereafter until Governance determines sustained compliance is achieved. 10. Monitoring of services furnished in the hospital, whether or not they are furnished under contract, are included in the organization's QAPI program, with outcome indicator reporting pursuant to the monthly reporting schedule related to the service provided. Examples include monthly compliance rates with proper surgical instrument sterilization, adequate staffing for SPD department functions, IUSS rates and SSI rates. 11 The Governing Board reviews the performance of contracted providers' ability to meet the organization's performance expectations set forth in the contract, including regulatory body requirements related to the provision of care, treatment and services, human resources and medical staff requirements as appropriate to the service provided. Contracted provider evaluation reports are provided to the Governing Board on an annual basis.	

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H 606	Continued From page 26 2/28/18, revealed IUSS was utilized on surgical instruments 60 times. During this timeframe, 21 instances had the reason documented for IUSS as the item was unsterile. e. On 2/28/18 at 3:17 p.m., an interview with SPD Director #4 was conducted. Director #4 stated using IUSS to sterilize surgical instruments was not ideal due to the potential contamination of surgical trays when transporting them from the autoclave to the operating room table. Director #4 stated IUSS could also be associated with infection if there was bioburden left on instruments. f. On 3/1/18 at 11:00 a.m., an interview was conducted with Infection Prevention Registered Nurse (IP RN) #9. IP RN #9 confirmed the facility followed AORN guidelines in the perioperative area, which included the minimized use of IUSS. IP RN #9 stated the risks involved with utilizing IUSS instead of the standard sterilization process would be contamination and infection. IP RN #9 stated IUSS should only be used in emergency situations; such as a life threatening surgery must be performed and IUSS of instruments was required to perform the surgery or a physician dropped and instrument. g. On 3/1/18 at 2:05 p.m., an interview with the chief nursing officer (CNO #7) was conducted. CNO #7 stated issues with staffing, leadership turnover and leadership oversight were all contributing factors for the routine use of IUSS. CNO #7 stated the issues of staffing and leadership oversight were due to leadership turnover and had been present for two years. 4. The facility failed to ensure staff responsible for infection prevention maintained a consistent process for identifying, investigating and reporting all potential surgical site infections (SSIs).	H 606		

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H 606	Continued From page 27 a. A review of Patient A's medical record revealed the patient had several visits to the facility for spine related issues. On 9/16/17 and 11/9/17, Patient A was admitted for elective surgeries which included procedures for a spinal fusion and laminectomy (removal of part of the vertebrae with intentions to release pressure on the spinal cord or nerves). On 1/1/18 at 7:03 a.m., Patient A arrived to the facility's emergency department (ED) via ambulance with a chief complaint of back pain. According to an Operative Note documented by Physician #21 on 1/3/18 at 8:00 p.m., a computed tomography (CT) scan identified a large amount of subcutaneous gas which was consistent with an infection. Physician #21 reported Patient A had a incision and drainage (I & D) procedure of the spinal surgical site wound. During the I & D procedure, fluid documented as white, milky and purulent (containing pus) was found throughout the entire surgical site. Samples of the fluid were sent to the laboratory for diagnostic testing. The postoperative diagnosis after the I & D procedure was documented as a postoperative infection. On 1/5/18 at 1:25 p.m., an Infectious Disease Progress Note documented the results of the purulent fluid diagnostic testing identified enterococcus faecalis (type of bacteria that causes infections). Patient A was treated with antibiotics and discharged to a skilled nursing facility (SNF) on 1/15/18. On 2/20/18 at 2:04 p.m., Patient A returned to the ED via ambulance from the SNF with a chief complaint of paraplegia (paralysis of the lower body). According to an Operative Note documented by Physician #22 at 5:00 p.m., Patient A underwent another I & D procedure where a significant amount of infectious looking material was collected and sent for diagnostic testing. On 2/23/18, the results of the diagnostic	H 606		

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H 606	Continued From page 28 testing identified enterococcus faecium (Vancomycin Resistant Enterococci or VRE) and staphylococcus on the intervertebral disc specimens obtained from the I & D procedure on 2/20/18. In addition, Patient A's blood tested positive for VRE on 2/23/18. b. During an interview with IP RN #9 on 4/11/18 at 4:04 p.m., she stated she utilized multiple reports to track and investigate surgical site infections. IP RN #9 stated she was required to track and report certain SSIs to the National Healthcare Safety Network (NHSN). A request was made for all documentation of how she tracked and investigated possible SSIs and the criteria used to determine if they were reportable to NHSN. Review of the document titled 2018 SSI and utilized by IP RN #9 to track investigation and reporting of surgical site infections (SSIs), showed she had identified Patient A had a surgical site infection of the bone that met the criteria for being reported to the National Healthcare Safety Network (NHSN). However, upon review of the list of patients reported to NHSN for SSIs, Patient A was not listed as being reported for having an SSI. Seven additional patients were identified as meeting criteria for having a reportable SSI on the 2018 SSI document. Four of the seven patients were not documented as reported to NHSN (Patients #6, B, C, and D). On 4/12/18 at 2:00 p.m., Vice President of Quality (VP) #20 was interviewed. VP #20 provided documentation of the facility's tracking, trending and reporting of SSIs. She stated while gathering the documentation the facility noticed there were patients who had surgical site infections and should have been reported to NHSN but had not been, including Patient A. VP #20 stated IP RN #9 had too many	H 606		

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H 606	Continued From page 29 spreadsheets and no standard tracking format. VP #20 acknowledged the facility's current investigation and tracking of SSIs was not effective and they had "had missed the boat." She stated there was no standard tracking format and the individual responsible for the process was not competent to identify, investigate and track surgical site infections. During an interview with the Interim Director of Quality (Director #28), on 4/12/18 at 8:55 a.m., she stated since becoming the director she had identified concerns with the infection prevention program and was in the process of making some changes. However, Director #28 stated she had not instituted any changes at the time of the survey. 5. The facility identified an increase in surgical site infections (SSIs). However, the facility failed to follow through with an action plan to decrease SSIs and improve patient outcomes. a. A review of the Infection Prevention Committee minutes from 6/20/17 revealed an increase in hip and spine SSIs was first communicated to the committee in January 2017. The committee identified the rate of spinal SSIs had not improved since January 2017 and that an action plan had been created and a monthly meeting had been set up to regularly review the progress of the action plan. The monthly action plan meeting minutes were requested for review. Only two meetings were provided which occurred on 5/10/17 and 5/17/17. The corporate director of quality and patient safety (Director #23) acknowledged there was no documentation of monthly meetings and confirmed there were only two meetings held to review the action plan. The two monthly action plan review meetings identified possible interventions for reducing	H 606		

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H 606	Continued From page 30 spinal SSIs, including: ensuring the correct timing of preoperative antibiotics, conducting proper aseptic technique with hand hygiene and opening sterile packages prior to surgical procedures, evaluating staff applying skin prep to patients' surgical sites prior to incision, and cleaning of the OR after surgical procedures were completed. There was no further documentation to show if these interventions had been implemented, assessed or evaluated for effectiveness. In addition, according to the 2018 SSI document, there were eight patients identified with reportable spinal SSIs between 10/10/17 and 1/24/18 with no follow up from the monthly action plan review committee. On 3/1/18 at 11:00 a.m., an interview with Infection Preventionist (IP RN) #9 was conducted which revealed she had been in her position for 4 months. IP RN #9 stated she had not attended any meetings regarding a review of the action plan since she was hired. During a subsequent interview, on 4/11/18 at 4:03 p.m., IP RN #9 stated prior to February 2018 she was not aware of the "problem" with SSIs and she was "in shock" with the recent findings of contaminated instruments continuously being sent to the OR. 6. The facility failed to analyze data which had been collected to monitor the quality and effectiveness of the sterilization process and decrease the utilization of immediate use steam sterilization (IUSS) to ensure safe services and quality patient care. a. A review of the Sterile Processing Department (SPD) Case Reports log from 1/19/17 to 2/9/18 was conducted. During an interview with Clinical Nurse Specialist (CNS) #8, on 2/28/18 at 1:51 p.m., she stated the log contained data from SPD case reports which were completed by operating room staff who	H 606		

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H 606	Continued From page 31 discovered an issue after the tray was delivered to the operating room (OR) suite. According to CNS #8 the reports were sent down to SPD and the SPD manager created the log. Review of the case reports showed the following. As example, On 1/24/17 chunks of bone found inside of the pan. On 1/25/17 an instrument was noted as clogged with the previous patients blood. On 1/26/17 blood was found on a drill bit. On 2/16/17 cement was found on the instrumentation. On 3/8/17 visible bone and blood were found in the pan. On 3/22/17 bioburden was found while in a surgical case. On 4/21/17 blood was found on top of spinal surgical instruments (rainbow curettes). On 6/1/17 an instrument was found to have dried blood on it. On 6/28/17 black residue was found on an instrument. On 6/29/17, OR staff documented a dead bug was found in the surgical tray. On 8/28/17 crusty blood or tissue was found on a surgical instrument. On 11/22/17 blood from a previous surgical case was found on a piece of an instrument. On 1/23/18 a piece of bone was found in the bottom of the tray. On 2/19/18 hair was found on surgical instruments. On 3/12/18 bone was found in the bottom of the tray and "contaminated" the "entire setup." On 3/29/18 "rust/blood" was found on a drill. On 4/2/18 questionable residue was found on instruments which "lead to cancellation of surgery." Specifically, the facility identified 76 instances of contaminated surgical instruments and trays,	H 606		

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H 606	Continued From page 32 from 1/1/17 to present, which had been processed in SPD and sent to the OR suite to be utilized in surgical cases. b. During an interview, on 4/12/18 at 8:55 a.m., Interim Director of Quality (Director) #28, stated the facility implemented an improvement project (LEAN project) to improve surgery delay times but she was not directly involved in the project. During the project the value optimization team reviewed the Case Reports as a way to measure the success of the project and identify "defects" (variations) from the improvement process. According to Director #28 she was not aware the case reports existed and they were not being reported to the quality department. Director #28 stated the optimization team did not look at the case reports with a patient "safety lens." She acknowledged "we were not effective or efficient on acting" on sterilization issues identified on the case reports as she was not aware of them. c. On 2/28/18 at 11:54 a.m., an interview was conducted with the surgical clinical nurse specialist (CNS #8), who stated she was responsible for collecting data regarding IUSS and incidents involving the sterility of surgical instruments delivered to the OR. CNS #8 stated she noticed an increase of instruments utilizing IUSS cycles due to the sterile processing department (SPD) not having time to complete a full standard sterilization cycle. CNS #8 also identified an increase of incidents regarding instruments being opened in the OR with bioburden on them, specifically blood, bone or cement from a prior case. CNS #8 stated she notified her boss (Director #4) about her findings in April 2017. CNS #8 further stated a LEAN project was created related to the findings of ongoing IUSS utilization and contaminated instruments. CNS #8 stated she had attended the first few LEAN	H 606		

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H 606	Continued From page 33 project meetings, but was not aware of any ongoing discussions about the project since May 2017. 7. The facility failed to ensure SPTs contracted for employment in the sterile processing department (SPD) were qualified and met the criteria agreed upon in the contract between the facility and the SPT's employment agency and deemed competent prior to providing services. a. On 4/10/18 at 3:00 p.m., two contracted SPTs (SPT #25 and SPT #26) were observed cleaning surgical instruments in the decontamination room. The SPTs were also observed by a contracted infection prevention consultant (Consultant #27), who stated she was conducting audits of SPTs performing instrument decontamination, cleaning and sterilizing tasks in the SPD. SPT #26 was observed scrubbing kerrisons (spinal surgical instruments) with a brush in a sink partially filled with water and enzymatic solution. SPT #26 required verbal feedback from Consultant #27 that he did not scrub the kerrisions for a full minute which was in accordance with the manufacturer's instructions. When SPT #26 was finished with cleaning the kerrisons, Consultant #27 instructed SPT #26 that he still needed to flush the instruments with water. SPT #25 was then observed scrubbing kerrisons with a brush in the same sink. SPT #25 required guidance from Consultant #27 on properly flushing and rinsing the instruments in accordance with manufacturer's instructions before moving on to the next step in the instrument cleaning process. b. A review of a contract between the facility and an employment agency revealed the agency would provide the facility with qualified SPTs	H 606		

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H 606	Continued From page 34 internationally certified through the International Association of Healthcare Central Service Material Management (IAHCSMM) or the Certification Board for Sterile Processing Distribution (CBSPD). Review of SPT #25's personnel file, hired through the agency, revealed no evidence he was certified as required by the contract. On 4/12/18 at 5:00 p.m., Manager #24 stated SPT #25 was not certified and did not meet the terms required in the contract. Additionally, personnel file review of five contracted SPTs (#25, #26, #29, #30, and #31) showed that although each employee had filled out a self evaluation there was no evidence the facility had evaluated the SPTs to ensure they were competent in duties there were assigned in the sterilization process. (Cross reference 503, 504, 610 and 901)	H 606		
A 610	3.1 Qlty Mgt, Occ Rpt, PC-Qlty Mgt Prgm QUALITY MANAGEMENT PROGRAM Every health care entity licensed or certified by the Department pursuant to Section 25-1.5 -103(1)(a), C.R.S., shall establish a quality management program appropriate to the size and type of facility that evaluates the quality of patient or resident care and safety, and that complies with this Part 3. Assisted living residences and community residential homes shall have until December 31, 2015, to achieve full compliance with this regulation . This REGULATION is not met as evidenced by: Based on interviews and document reviews, the facility failed to maintain an ongoing quality program that identified and tracked quality data and implemented changes to improve patient	A 610	Tag A 610: Quality Management	06/27/2018

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A 610	Continued From page 35 outcomes. This failure resulted in ongoing incidents in which contaminated surgical instruments were being delivered to the operating room (OR) for surgical cases and potentially contributed to an increase in surgical site infections and adverse patient events. Findings include: References: According to the Quality Assessment, Patient Safety and Performance Improvement Plan, dated 11/16/17, the facility will utilize information from risk assessments and ongoing data analysis to make changes that will improve quality, performance and patient safety and reduce the likelihood and risk of sentinel events and other adverse events. 1. The facility failed to analyze data which had been collected to monitor the quality and effectiveness of the sterilization process and decrease the utilization of immediate use steam sterilization (IUSS) to ensure safe services and quality patient care. a. A review of the Sterile Processing Department (SPD) Case Reports log, from 1/19/17 to 2/9/18, was conducted. During an interview with Clinical Nurse Specialist (CNS) #8, on 2/28/18 at 1:51 p.m., she stated the log contained data from SPD case reports which were completed by operating room staff who discovered an issue after the tray was delivered to the operating room (OR) suite. According to CNS #8 the reports were sent down to SPD and the SPD manager created the log. Review of the case reports showed the following, as example: On 1/24/17 chunks of bone found inside of the pan.	A 610	Person Responsible: The Governing Board will have ultimate responsibility for all corrective actions and ongoing compliance associated with these requirements, however the Chief Nursing Officer) CNO and Chief Medical Officer (CMO) provide direct oversight. Actions: 1. The Governing Board has full responsibility for determining, implementing and monitoring the Hospital's total operations and compliance with its policies and procedures. 2. The Governing Board was informed of the outcome of accreditation surveys occurring 2/20/18 forward, via phone calls and meetings. The Governing Board held regular meetings and conference calls, late February forward, to discuss the survey findings and the plans of correction. 3. The Governing Board meets monthly, and as necessary, to discuss overall operational and patient care issues, related but not limited to, effectiveness of quality management, performance improvement and occurrence reporting. Hospital leadership worked closely with Centura corporate leadership to assist with correction of survey findings and implementation of processes to sustain compliance. 4. QAPI Plan revised, including quality reporting structure and Quality Calendar of Reporting, reviewed and approved by Quality Council 5/9/18 Approved by the Quality Committee of the Board and the Governing Board on 5/24/18. 5. Governing Board review of Board Bylaws and Responsibility Matrix to	

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A 610	Continued From page 36 On 1/25/17 an instrument was noted as clogged with the previous patient's blood. On 1/26/17 blood was found on a drill bit. On 2/16/17 cement was found on the instrumentation. On 3/8/17 visible bone and blood were found in the pan. On 3/22/17 bioburden was found while in a surgical case. On 4/21/17 blood was found on top of spinal surgical instruments (rainbow curettes). On 6/1/17 an instrument was found to have dried blood on it. On 6/28/17 black residue was found on an instrument. On 6/29/17 OR staff documented a dead bug was found in the surgical tray. On 8/28/17 crusty blood or tissue was found on a surgical instrument. On 11/22/17 blood from a previous surgical case was found on a piece of an instrument. On 1/23/18 a piece of bone was found in the bottom of the tray. On 2/19/18 hair was found on surgical instruments. On 3/12/18 bone was found in the bottom of the tray and "contaminated" the "entire setup." On 3/29/18 "rust/blood" was found on a drill. On 4/2/18 questionable residue was found on instruments which "lead to cancellation of surgery." Specifically, the facility identified 76 instances of contaminated surgical instruments and trays, from 1/1/17 to present, which had been processed in SPD and sent to the OR suite to be utilized in surgical cases. b. On 2/27/18 at 10:27 a.m. an interview with SPD Manager #3 was conducted. Manager #3 stated "we are short staffed" and we're currently processing instruments for up to 50 cases a day which he considered to be "not safe." He stated "I don't have enough staff" and the sterile	A 610	ensure Board understanding of roles and responsibilities on 5/24/18. 6. Unit/department managers are responsible for identifying relevant performance improvement (PI) projects in collaboration with facility quality and PI/LEAN experts. PI initiatives are now reported to the Governing Board on a scheduled basis. 7. PI projects are prioritized by Quality Council, based on clinical need, regulatory requirements and alignment with organizational goals. LEAN projects are fully integrated into the quality structure as of 4/25/18 and are included in quality and safety reporting to the Governing Board. 8. PI projects are included in Quality Council meeting agenda and planning and reviews for closure to ensure follow-up activities are properly addressed, timeframes to be determined by specifics of the projects, as of 5/31/18. 9. PI projects now include surgical and sterilization processes, SPD flow and compliance with infection prevention safe practices, including IUSS. 10. Incidences of dirty case cart fall-outs, previously reported on paper documents and sent to Sterile Processing Department (SPD) and incidences of inadequately sterilized instruments are now entered into the electronic occurrence reporting system for review, tracking and trending, as of 2/21/18. 11. Infection Preventionists (IP) are responsible for infection data and reporting of SSIs. SSI data is reported up through the Infection Prevention	

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A 610	Continued From page 37 processing department was "severely short staffed." Manager #3 stated he was aware there were stil contaminated trays being delivered to the operating room recently after the sterilization process had been completed. He reported he did not have time to audit instruments after SPD staff completed the precleaning process and prior to the instruments being sterilized. He stated he had to wait for an incident report to be completed by OR staff to identify contaminated trays or instruments. However, there was no documentation the facility had identified the ongoing issue of contamination within SPD and implemented corrective actions in order to improve quality and patient safety and reduce the likelihood and risk of sentinel events and other adverse events. c. During an interview, on 4/12/18 at 8:55 a.m., Interim Director of Quality (Director) #28 stated the facility implemented an improvement project (LEAN project) to improve surgery delay times but she was directly involved in the project. During the project the value optimization team reviewed the Case Reports as a way to measure the success of the project and identify "defects" (variations) from the improvement process. According to Director #28 she was not aware the case reports existed and they were not being reported to the quality department. Director #28 stated the optimization team did not look at the case reports with a patient "safety lens." She acknowledged "we were not effective or efficient on acting" on sterilization issues identified on the case reports and she was not aware of them. d. On 2/28/18 at 11:54 a.m., an interview was conducted with the surgical clinical nurse specialist (CNS #8), who stated she was responsible for collecting data regarding	A 610	Committee OR Committee, Quality Council, and to Quality Committee of the Board. The Governing Board will receive updated data at each meeting to ensure their ability to monitor trends and have oversight and responsibility for outcomes. 12. The Quality Calendar of Reporting was modified to include reports to the Quality Council of occurrences of inadequately pre-cleaned and or inadequately sterilized instruments, IUSS rates and other improvement activities undertaken to remediate inadequate SPD instrument cleaning/sterilization – 5/9/18 Compliance and Monitoring: 1. Quality Council meets monthly, consistently, and follows the quality reporting structure and Quality Calendar of Reporting. 2. Data reported at Quality Council, related to surgical instrument sterility, Immediate Use Steam Sterilization (IUSS) and Surgical Site Infections (SSI) is reported from OR Committee and/or IP Committee and on to the Governing Board monthly. 3. IUSS rates reported to Infection Prevention Committee and to Quality Council monthly – initiated 4/25/18. 4. OR/SPD monitoring dashboard developed; process and outcome data for OR and SPD, including infection prevention-related data, is reported to Quality Council monthly – week of 5/28/18. 5. NHSN Standardized Infection Ratio is monitored. 6. SSI data is monitored and reported	

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A 610	Continued From page 38 immediate use steam sterilization (IUSS) and incidents involving the sterility of surgical instruments delivered to the OR. CNS #8 stated she noticed an increase of instruments utilizing IUSS cycles due to SPD not having time to complete a full standard sterilization cycle. CNS #8 also identified an increase of incidents regarding instruments being opened in the OR with bioburden on them, specifically blood, bone or cement from a prior case. CNS #8 stated she notified her boss (Director #4) about her findings in April 2017. CNS #8 further stated a LEAN project was created related to the findings of ongoing IUSS utilization and contaminated instruments. CNS #8 stated she had attended the first few LEAN project meetings, but was not aware of any ongoing discussions about the project since May 2017. 2. The facility identified an increase in surgical site infections (SSIs). However, the facility failed to follow through with an action plan to decrease SSIs and improve patient outcomes. a. A review of the Infection Prevention Committee minutes from 6/20/17 revealed an increase in hip and spine SSIs was first communicated to the committee in January 2017. The committee identified the rate of spinal SSIs had not improved since January 2017 and that an action plan had been created and a monthly meeting had been set up to regularly review the progress of the action plan. The monthly action plan meeting minutes were requested for review. Only two meetings were provided which occurred on 5/10/17 and 5/17/17. The corporate director of quality and patient safety (Director #23) acknowledged there was no documentation of monthly meetings and confirmed there were only two meetings held to review the action plan.	A 610	monthly to Infection Prevention Committee, OR Committee and Quality Council and to the Governing Board quarterly as a component of routine infection prevention and control processes.	

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A 610	Continued From page 39 The two monthly action plan review meetings identified possible interventions for reducing spinal SSIs, including: ensuring the correct timing of preoperative antibiotics, conducting proper aseptic technique with hand hygiene and opening sterile packages prior to surgical procedures, evaluating staff applying skin prep to patients' surgical sites prior to incision, and cleaning of the OR after surgical procedures were completed. There was no further documentation to show if these interventions had been implemented, assessed or evaluated for effectiveness. In addition, according to the 2018 SSI document, there were eight patients identified with reportable spinal SSIs between 10/10/17 and 1/24/18 with no follow up from the monthly action plan review committee. On 3/1/18 at 11:00 a.m., an interview with Infection Preventionist (IP RN) #9 was conducted which revealed she had been in her position for 4 months. IP RN #9 stated she had not attended any meetings regarding a review of the action plan since she was hired. During a subsequent interview, on 4/11/18 at 4:03 p.m., IP RN #9 stated prior to February 2018 she was not aware of the "problem" with SSIs and she was "in shock" with the recent findings of contaminated instruments continuously being sent to the OR. (Cross reference 0749, 0941 and 0951)	A 610		
H 901	IV.9.101(1) Infection Control: Providing Service The facility shall have an infection control program responsible for reducing the risk of acquiring and transmitting nosocomial infections and infectious diseases in the facility.	H 901		06/27/2018

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H 901	Continued From page 40 This REGULATION is not met as evidenced by: Based on observations, document review and interviews the facility failed to ensure surgical services were provided in accordance with established standards of care to ensure positive patient outcomes; specifically related to the routine use of Immediate Use Steam Sterilization (IUSS), a lack of oversight provided to the sterile processing department staff and vendor representatives. Additionally, the facility failed to identify, track, and trend surgical site infections. This failure resulted in ongoing use of IUSS and the potential for transmission of healthcare acquired infections. Additionally, the failure resulted in surgical site infections not being investigated and reported to identify potential trends and areas for improvement. Findings include: Facility Policy: The Sterile Processing Procedures policy read, use of immediate use steam sterilization (IUSS) will be kept to a minimum and only utilized in selected clinical situations when there is insufficient time to process by the preferred wrapped or container method. Vendors will have checked in at the designated vendor management system kiosk, donned appropriate ID and attire, prior to entering the Sterile Processing Department (SPD). The Surgical Attire policy read, clothing including long sleeved garments that cannot be covered by surgical attire shall not be worn in the restricted or semi-restricted areas. Non-scrubbed personnel should wear long-sleeved jackets in restricted areas. A clean, low lint surgical head cover that confines hair will be worn when in semi-restricted and restricted areas of the surgical suite.	H 901	Tag H 901: Infection Control Person Responsible: The Governing Body will have ultimate responsibility for all corrective actions and ongoing compliance associated with this requirement, however the Chief Nursing Officer) CNO provides direct oversight. The Infection Prevention RN, CNO and Director(s) of Perioperative Services collaborated regarding the routine use of IUSS with the goal if ensuring that instrumentation is ready and available, thereby reducing the rate of IUSS. The Infection Prevention RN collaborated with leadership regarding oversight of SSIs, and oversight of SPD vendor representatives. An IP consultant was contracted to review IP-related SPD operations. Actions: 1. The Governing Board has full responsibility for determining, implementing and monitoring the Hospital's total operations and compliance with its policies and procedures. 2. The Governing Board was informed of the outcome of accreditation surveys occurring 2/20/18 forward, via phone calls and meetings. The Governing Board held regular meetings and conference calls, late February forward, to discuss the survey findings and the plans of correction. 3. The Governing Board meets monthly and as necessary to discuss overall operational and patient care issues, related but not limited to, effectiveness of sterilization and infection control program	

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H 901	Continued From page 41 The Vendor Instrumentation policy read, all pans must be received by 2:00 p.m. the day prior to surgery. Monday cases need to be received by 2:00 p.m. the Friday before surgery is scheduled. The Universal Protocol policy read, the elements on the Surgical Safety Checklist were selected to ensure that additional elements considered essential to patient safety were consistently addressed prior to procedures. The standardized list will include verification during the time out that devices or special equipment are available. The Surveillance policy read, data is collected on all patients that meet the National Healthcare Safety Network (NHSN) criteria for a hospital acquired infection. Surveillance information is also uploaded into the NHSN database as required by the Colorado Department of Public Health and Environment. The Infection Prevention & Control Program policy read, the committee shall oversee and review surveillance and reporting data of the facility's infection prevention and control program. The Infection Preventionist is responsible for coordinating day-to-day services. To fulfill the purpose of this program, the Infection Preventionist will develop and implement a targeted surveillance program and maintain current certification in infection prevention and control. References: According to The Association of Perioperative Registered Nurses (AORN), Guidelines for Perioperative Practice, 2017: Recommendation VII (Page 871), IUSS may be associated with an increased risk of infection to	H 901	and practices. Hospital leadership worked closely with Centura corporate leadership to assist with correction of survey findings and implementation of processes to sustain compliance. 4. Instrument sterilization was addressed through increase of SPD staff and SPD staff management. An Interim, experienced SPD Manager was hired through a contract agency and began on 4/10/18 to provide review and oversight of industry-standard protocols used for decontamination and sterilization. The SPD Manager has responsibility for SPD staffing and process, ensuring that instruments are ready for scheduled cases. 5. Staff scheduling was reviewed and revised. Staffing has increased on all shifts. By 4/20/18 a balanced staffing schedule was complete, including off-shift coverage. This schedule modified coverage by developing a 6-week schedule and adding experienced traveler SPD staff, trained and competent in decontamination and sterilization, as they are available and oriented. 6. Immediate Use Steam Sterilization (IUSS) rates were reviewed and addressed at a monthly Surgery Department Operating Review (DOR) meeting on 5/16/18, held by the Chief Medical Officer and the Director of Quality, which includes review of IUSS rates, occurrences and identifies opportunities for IUSS reduction. Incidents of IUSS of implant are entered into the occurrence reporting system for tracking and trending. 7. SPD and OR staff initiated training	

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H 901	Continued From page 42 patients and should be kept to a minimum. 1. The facility failed to ensure surgical instruments needed for surgeries were sterilized and available for use at the scheduled start time of patients' surgeries. a. On 2/27/18, a surgical case tracer scheduled for 7:30 a.m. was observed. At 6:55 a.m., Certified Surgical Technician (CST) #10 stated she went to the sterile processing department (SPD) prior to setting up for the case and instruments required for the current case were still cooling. CST #10 stated she frequently had to wait for instruments to be delivered from the SPD at the start of the day. At 7:34 a.m., OR Manager #5 called the SPD to ascertain when the instruments would be ready. Manager #5 stated the staff member from the SPD she spoke with reported the instruments would be ready for delivery to the OR suite in 10 to 15 minutes. At 7:50 a.m., 20 minutes after the scheduled surgery start time, several surgical instrument trays arrived to the OR suite. At 9:30 a.m., a time out occurred with all staff present in the OR suite and Vendor #15. The entire team participated, including Vendor #15, with no equipment comments or concerns identified. The time out included verbal verification that all sterilized instruments required for the case were present. At 9:36 a.m., Physician #17 made the first incision. At 9:44 a.m., Vendor #15 brought another tray of surgical instruments into the OR suite and stated he had to wait for them to cool prior to bringing them into the operating room. When asked about the late tray, Vendor #15 stated he should have spoken up during the timeout to notify the team that the tray was unavailable and was still cooling in the SPD. At 9:44 a.m., OR Manager #5 was interviewed	H 901	and education on IUSS policy and procedure on 5/7/18. This training includes IUSS of implants, with proper biological indicator reading conducted prior to implantation. 8. 2 IUSS sterilizers have been removed from service as of the week of 5/14/18 and an additional 3 will be decommissioned by 7/1/18. 9. The Perioperative Director or designee is notified of each episode of IUSS, for consideration of use outside usual guidelines. 10. A retrospective review of IUSS episodes from 4/1/18 forward, will be performed to review and track reasons for IUSS, as a point of reference to assist to ensure that IUSS is used appropriately. 11 Infection Prevention measures were reviewed. A position of Infection Control Manager was posted 4/13/18 and an IP was hired; started 5/16/18. The IP's orientation scope will be determined after initial competency assessment is completed; orientation to be completed prior to 90 days post-hire. Orientation will be facilitated and monitored by an experienced and competent IPs from other system facilities. A contract for an agency IP to provide additional IP support was signed 5/7/18 and started 5/25/18. 12. A comprehensive review of possible SSI cases from 7/17 to present will be conducted, to ensure that all SSIs were/are captured, trends identified and appropriately reported through NHSN and the hospital's internal infection tracking	

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H 901	Continued From page 43 and stated the facility's expectation was for all needed surgical trays to be sterilized and available prior to the patient entering the OR suite. Manager #5 further stated she would have expected a discussion from Vendor #15 about the delay of the surgical tray arriving to the OR suite during the time out. On 2/27/18 at 4:05 p.m., CST #10 was interviewed. CST #10 stated she thought all of the necessary surgical instruments were in the OR suite and available when the OR team verified all instrumentation was in the room during the time out. CST #10 further stated all of the instrumentation needed for the procedure should have been in the room prior to the incision. CST #10 stated that case carts were not always stocked properly because sterile instruments were not ready when they were needed. b. On 2/27/18 at 7:50 a.m., an observation in the sterile OR corridor revealed an oculoplasty set (instrumentation used for surgical procedures involving structures around the eyes) was undergoing an immediate use steam sterilization (IUSS) cycle in autoclave #9. Further observation in the sterile operating room corridor revealed an ear, nose and throat drill set undergoing an IUSS cycle in autoclave #2 for the same patient awaiting the oculoplasty set. Registered Nurse (RN) #11 removed the tray from autoclave #2 and stated the tray of instruments was not ready when the surgery was scheduled to start which required the use of IUSS for those instruments. Scrub Technician (ST) #12 verified the instrument tray required IUSS because it was not sterile at the beginning of the day. During the observation in the sterile OR corridor, Manager #5 confirmed the reason the oculoplasty tray required IUSS was it was not sterilized by the SPD in time for the surgery start	H 901	system. Daily positive culture reports are reviewed, possible SSIs are flagged based on symptoms and readmission log. This process is a routine component of the Infection Prevention and Control program. 13. The National Healthcare Safety Network (NHSN) definition and algorithm are followed for SSI and reporting criteria. Infections meeting NHSN criteria will be reported. 14. SSI surveillance letters were sent to physicians who performed surgeries from 7/17 to present, week of 5/14/18. 15. IP ensures consistent follow-up for identifying, investigating and reporting SSIs. A standardized SSI tracking system was developed and implemented on 5/8/18 and IP trained on system 5/8/18. Pivot table to track/report to be built week of 5/14/18 and future state solution to track SSIs in EPIC (the hospital's electronic medical record) is in development at the corporate level. 16. IP consultant, with expertise in SPD and perioperative services was retained starting 4/9/18 through 5/4/18. Recommendations were provided to the CNO at exit on 5/4/18 with emphasis on leadership recommendations, instrument tracking and organization/vendor management and need for consistent work processes. Recommendations, per above, will be considered and implemented as appropriate. 17. IP increased the rate of surveillance in the OR with attention to the pre-cleaning of surgical instruments and in decontamination and sterilization in SPD,	

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H 901	Continued From page 44 time. c. On 2/28/18 at 11:54 a.m., an interview with Clinical Nursing Specialist (CNS) #8 was conducted. CNS #8 stated the SPD did not have enough "man power" to meet the work demand resulting in instruments processed utilizing IUSS. CNS #8 continued by stating if there was not enough SPD staff available to meet the scheduled work load, the department would always be behind in sterilizing surgical instruments. CNS #8 stated the main reason for the usage of IUSS was due to the inability to complete a full standard sterilization cycle in the SPD in time for the surgical case to begin. If surgical instruments were not sterilized by the start time of the surgical case, CNS #8 explained staff would at times utilize IUSS and document the reason for IUSS as the "item was unsterile." CNS #8 further stated IUSS was not an acceptable practice and should only be used in an emergency. d. A review of the IUSS logs, from 1/1/18 to 2/28/18, revealed IUSS was utilized on surgical instruments 60 times. During this timeframe, 21 instances had the reason documented for IUSS as the item was unsterile. e. On 2/28/18 at 3:17 p.m., an interview with SPD Director #4 was conducted. Director #4 stated using IUSS to sterilize surgical instruments was not ideal due to the potential contamination of surgical trays when transporting them from the autoclave to the operating room table. Director #4 stated IUSS could also be associated with infection if there was bioburden left on instruments. Director #4 added that she had discussed the need to have SPD staff participate in a flexible schedule in order to finish processing	H 901	as of 2/21/18. Surveillance includes review of precleaning /moistening of instruments at point-of-use in the OR, decontamination processes, review of SPD process and random selection and opening of surgical packs and sterilized cassettes/containers to identify variances in SPD final output. Just-in-Time coaching is provided to staff when appropriate. 18. E-mail communication sent to all vendor representatives on 3/26/18, through RepTrax for mandatory re-acknowledgement and re-acceptance of Centura vendor management policies, terms and conditions including surgical attire. 19. Vendors were refreshed, on 3/26/18, regarding the need to provide instruments needed for the following day, no later than 2PM on the day preceding the planned surgery (or the Friday before the following Monday). 20. When SPD verifies that drop-off timeframe expectations are not met, SPD notifies perioperative leadership to determine if SPD is able to accommodate late instruments in the SPD workflow. Perioperative leadership determines if the scheduled case may proceed or if it will be delayed/cancelled. 21. Perioperative leadership notifies Supply Chain Management when there is a need for vendor counseling. Supply Chain determines the need for and carries out vendor disciplinary action, for example, suspension. Compliance and Monitoring: 1. Daily monitoring of available SPD staff matching the staffing plan. Numerator = number of available SPD staff;	

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H 901	Continued From page 45 instruments from the prior day, keep up with the instruments for the current day and prepare for the next day. However, Director #4 explained there had been no changes in SPD staff scheduling implemented at the time of the survey. f. On 3/1/18 at 11:00 a.m., an interview was conducted with Infection Prevention Registered Nurse (IP RN) #9. IP RN #9 confirmed the facility followed AORN guidelines in the perioperative area, which included the minimized use of IUSS. IP RN #9 stated the risks involved with utilizing IUSS instead of the standard sterilization process would be contamination and infection. IP RN #9 stated IUSS should only be used in emergency situations. g. On 3/1/18 at 2:05 p.m., an interview with the chief nursing officer (CNO #7) was conducted. CNO #7 stated issues with staffing, leadership turnover and leadership oversight were all contributing factors for the routine use of IUSS. CNO #7 stated the issues of staffing and leadership oversight were due to leadership turnover and had been present for two years. 2. The facility failed to ensure staff responsible for infection prevention maintained a consistent process for identifying, investigating and reporting all potential surgical site infections (SSIs). a. A review of Patient A's medical record revealed the patient had several visits to the facility for spine related issues. On 9/16/17 and 11/9/17, Patient A was admitted for elective surgeries which included procedures for a spinal fusion and laminectomy (removal of part of the vertebrae with intentions to release pressure on the spinal cord or nerves). On 1/1/18 at 7:03 a.m., Patient A arrived to the	H 901	Denominator = number of SPD staff required per the staffing plan, with a compliance goal of 90%. 2. Monitoring of vacancy rate monthly for the next year and quarterly thereafter. Numerator = number of filled positions; denominator = total number of open positions per staffing matrix, with a compliance goal of 90%. 3. Status of SPD staffing, per above, will be reported to the Quality Council and Governing Board, monthly until Governance determines staffing levels are not contributing to failures in surgical instrumentation decontamination and sterilization and that staffing has stabilized with a solid recruitment and retention program implemented. 4. Checklist procedure requiring double-check sign-off of scrub tech and other OR designee to ensure point-of-use pre-cleaning and removal of gross bioburden and spraying of instruments with enzymatic instrument spray. A final check at point of departure from OR to SPD is performed to ensure lack of gross bioburden and presence of enzymatic spray. Fall-outs are entered into the occurrence reporting system for review and trending. 100% of carts are signed off at point-of-use and again at point of departure from the OR and prior to transport to SPD. Carts are monitored for at least 60 days, beginning 2/21/18. When 100% compliance is achieved for 60 days, monitoring will transition to a	

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H 901	Continued From page 46 facility's emergency department (ED) via ambulance with a chief complaint of back pain. According to an Operative Note documented by Physician #21, on 1/3/18 at 8:00 p.m., a computed tomography (CT) scan identified a large amount of subcutaneous gas which was consistent with an infection. Physician #21 reported Patient A had a incision and drainage (I & D) procedure of the spinal surgical site wound. During the I & D procedure, fluid documented as white, milky and purulent (containing pus) was found throughout the entire surgical site. Samples of the fluid were sent to the laboratory for diagnostic testing. The postoperative diagnosis after the I & D procedure was documented as a postoperative infection. On 1/5/18 at 1:25 p.m., an Infectious Disease Progress Note documented the results of the purulent fluid diagnostic testing identified enterococcus faecalis (type of bacteria that causes infections). Patient A was treated with antibiotics and discharged to a skilled nursing facility (SNF) on 1/15/18. On 2/20/18 at 2:04 p.m., Patient A returned to the ED via ambulance from the SNF with a chief complaint of paraplegia (paralysis of the lower body). According to an Operative Note documented by Physician #22 at 5:00 p.m., Patient A underwent another I & D procedure where a significant amount of infectious looking material was collected and sent for diagnostic testing. On 2/23/18, the results of the diagnostic testing identified enterococcus faecium (Vancomycin Resistant Enterococci or VRE) and staphylococcus on the intervertebral disc specimens obtained from the I & D procedure on 2/20/18. In addition, Patient A's blood tested positive for VRE on 2/23/18. b. During an interview with IP RN #9 on 4/11/18 at 4:04 p.m., she stated she utilized multiple reports to track and investigate surgical site	H 901	random audit of 75 case carts per week for one month. When 100% compliance is sustained for one month, an audit of 75 random carts per month will occur for one month. 5. Monitoring of failures in proper decontamination and/or sterilization on an as occurrence basis to ensure remedial action is taken. Numerator = number of reported decontamination/sterilization failures monthly; Denominator = number of surgical cases performed monthly with a goal of 0% failure rate. 6. Monitoring of completion of counseling/ corrective action in relationship to each identified failure. Numerator = number of corrective actions documented related to failures monthly; Denominator = number of occurrence reports related to SPD process fall-out occurrences monthly, with a goal of 100% compliance. 7. Monitoring of IUSS rate and reasons will be conducted monthly, including IUSS of implants. Numerator = number of instruments and instrument sets receiving IUSS; denominator = number of surgical cases, with an IUSS target goal of 5% due to inadequately sterilized instruments vs. dropped or inadvertently contaminated during procedures, and a target goal of 0% for implants. 8. SSI data is tracked and trended, along with the NHSN SIR. 9. Supply Chain monitors the SPD vendor sign-in form, for timeliness of vendor instrument set deliveries, and for compliance with surgical attire.	

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H 901	Continued From page 47 infections. IP RN #9 stated she was required to track and report certain SSIs to the National Healthcare Safety Network (NHSN). A request was made for all documentation of how she tracked and investigated possible SSIs and the criteria used to determine if they were reportable to NHSN. Review of the document titled 2018 SSI and utilized by IP RN #9 to track investigation and reporting of surgical site infections (SSIs), showed she had identified Patient A had a surgical site infection of the bone that met the criteria for being reported to the National Healthcare Safety Network (NHSN). However, upon review of the list of patients reported to NHSN for SSIs, Patient A was not listed as being reported for having an SSI. Seven additional patients were identified as meeting criteria for having a reportable SSI on the 2018 SSI document. Four of the seven patients were not documented as reported to NHSN (Patients #6, B, C, and D). On 4/12/18 at 2:00 p.m., Vice President of Quality (VP) #20 was interviewed. VP #20 provided documentation of the facility's tracking, trending and reporting of SSIs. She stated while gathering the documentation the facility noticed there were patients who had surgical site infections and should have been reported to NHSN but had not been, including Patient A. VP #20 stated IP RN #9 had too many spreadsheets and no standard tracking format. VP #20 acknowledged the facility's current investigation and tracking of SSIs was not effective and they had "had missed the boat." She stated there was no standard tracking format and the individual responsible for the process was not "competent" to identify, investigate and track surgical site infections. During an interview with the Interim Director of	H 901	10. IP surveillance conducted weekly with compliance goal of 4 tracers a month for 4 months, followed by 2X/month for 2 months and at least quarterly thereafter. Outcomes of surveillance are communicated to OR and SPD leadership weekly. 11 Data will be reported to the OR Committee, Infection Prevention Committee, Quality Council and the Governing Body monthly, for a period of 4 months and quarterly thereafter until Governance determines that sustained compliance has been achieved.	

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H 901	Continued From page 48 Quality (Director #28), on 4/12/18 at 8:55 a.m., she stated since becoming the director she had identified concerns with the infection prevention program and was in the process of making some changes. However, Director #28 stated she had not instituted any changes at the time of the survey. 3. The facility failed to provide oversight to ensure vendor loaned surgical instruments were delivered to the facility to be processed by the time required by facility policy. a. On 2/27/18, a surgical case tracer scheduled for 7:30 a.m. was observed. At 7:50 a.m., 20 minutes after the scheduled surgery start time, several vendor supplied surgical instrument trays arrived to the OR suite. At 9:36 a.m., Physician #17 made the first incision. At 9:44 a.m., Vendor #15 brought in another tray of vendor surgical instruments into the OR suite and stated he had to wait for them to cool prior to bringing them into the operating room. At 9:44 a.m., OR Manager #5 was interviewed and stated the facility's expectation was for all needed surgical trays to be sterilized and available prior to the patient entering the OR suite. On 2/27/18 at 10:27 a.m., an interview with SPD Director #4 was conducted. Director #4 stated vendors were expected to bring surgical instruments to the SPD no later than 2:00 p.m. the day prior to the surgery in which they were intended to be used. Director #4 stated that all vendors were tracked when entering and exiting the facility through a computer system called Rep Tracks. Director #4 stated she was unaware of any auditing done of vendor's work and that this was something the SPD could improve on.	H 901		

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H 901	Continued From page 49 A review of Rep Tracks was conducted and revealed Vendor #15 delivered instruments for Patient #12's surgery on 2/26/18 at 3:16 p.m. This was 76 minutes after the 2:00 p.m. expectation for vendors to deliver instruments to the sterile processing department prior to procedures to allow for enough time for the standard sterilization process. 4. The facility failed to ensure outside vendors followed facility policy regarding required attire ir the sterile processing department. a. On 2/27/18 at 10:05 a.m., a tour of the sterile processing department was conducted with SPD Manager #3. Vendor #16 was observed setting up clean instruments in trays to be sterilized. Vendor #16 was not wearing a surgical hair cover and was wearing a personal long sleeve shirt under a surgical scrub top without a surgical scrub jacket. Vendor #16 left the room briefly and returned with a surgical hair cover on and a surgical scrub jacket on over his long sleeve shirt and the scrub shirt. b. On 2/27/18 at 10:27 a.m., an interview with SPD Director #4 was conducted. Director #4 stated the expectation was for vendors to wear surgical scrubs including a jacket, shoe covers and hair covers while processing instruments. Director #4 stated any vendors not complying with those requirements were expected to be escorted out of the area immediately.	H 901		